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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,294	12/21/2000	Kristin Robert Stroda	638-29-9-1	1862

7590

05/20/2003

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EXAMINER

LIEU, JULIE BICHNGOC

ART UNIT	PAPER NUMBER
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2632

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/746,294

Applicant(s)

STRODA ET AL.

Examiner

Julie Lieu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24-27 and 29 is/are allowed.
- 6) ☒ Claim(s) 1-15, 17-23, 28, 30 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. This Office action is in response to amendment filed February 24, 2003. Claims 1, 17, 22-25, 27-31 have been amended.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

3. Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear whether the alarm is activated after the pressure is removed longer than a predetermined time or is it activated upon a release of the pressure? (lines 7-9).

Claim Rejections - 35 USC § 102

4. Claims 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Boon (US Patent No. 5,796,059).

Claim 11:

Boon discloses a system for monitoring a patient, comprising:

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- a. a pressure pad for providing a signal indicating a pressure condition;
- b. a control housing connected to the pressure pad and responsive to the signal; and
- c. a casing 52 at least partly encasing the pressure pad.

Claim 12:

The pressure pad in Boon is activated by removal of pressure and inactivated by application of pressure.

5. Claims 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Cross (US Patent No. 5,494,046).

Claim 7:

Cross discloses a method of monitoring a patient, comprising the steps of:

- a. placing a pressure pad under the patient that activates a first switch when energized (fig. 5 or 6)
- b. attaching a fastener (fig. 4) to the patient, wherein if the patient moves beyond a predetermined distance, a second switch moves between one of an open state of a closed state to the other of the open and closed state
- c. providing an alarm signal when either the first or second switch is activated wherein the pressure pad is activated by removal of pressure and reset by application or pressure.

Claim 8:

The fastener is attached to the clothing of the patient. Fig. 4.

Claim 9:

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Cross's system provide verbal message to the patient (col. 3, lines 46-50).

Claim 10:

Cross transmits a signal to a remote station and providing an alarm to a caretaker at the remote station.

Claim Rejections - 35 USC § 103

6. Claims 1, 3, 6, 14, 15, and 26-27 are rejected under 35 U.S.C. 102(3) as being unpatentable over Boon (US Patent No. 5,796,059).

Claim 1:

Boon discloses a method of monitoring a patient, comprising the steps of:

- a. placing a pressure pad (including 52) on a resting place, a bed or a chair, for the patient;
- b. energizing the pressure pad, whereby a signal is provided responsive to pressure more than a predetermined pressure being placed on the pressure pad by the patient (a minimum pressure that causes the detection);
- c. applying pressure above the predetermined pressure to the pressure pad (patient lying on the pad)
- d. arming the pressure pad when the pressure more than a predetermined pressure a predetermined weight the detection is on the pressure pad whereby the pressure pad serves as a sensor;

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- e. activating an alarm when the predetermined pressure has been on and then is removed from the armed pressure pad
- f. disposing of the pressure pad when the patient no longer has use of the pressure pad.

Regarding the claimed preventing activating the alarm when the pressure has been on the pad for more than a predetermined time and the release of the pressure are separated in time more than a preset period of time, it would have been obvious to one skilled in the art to consider some time delays because false alarm would be preferable avoided and alarm should only be given during actual use of the pressure, whereas unintentional activation of the alarm could happen such as when health personnel might happen to press against the pad while setting up the bed for patient to use or inadvertent movement of patient on the bed causing false alarm to go off.

Further, one skilled in the art would have readily recognized that the situation wherein the pressure has been applied on the pad for some time and removed from the pad for some time would most likely a situation that the patient is actually using the pad and left the pad. Therefore, one skilled in the art would apply such concept into the Boon system because it would prevent false alarms.

Regarding the claimed disposing the pad when patient no longer has use of the pressure pad without permitting use by another patient, it would have been obvious to one skilled in the art that this is up to the implementer and/or user to decide whether the pad should be a disposable pad and would be discarded after each use of a patient for sanitary purposes.

Claim 3:

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Though not clearly stated, it would be inherent that an alarm is provided to a caretaker.

Claim 6:

The cover 52 of the pressure pad in Boon is plastic, however, it is not disposable. Nonetheless, the concept making a cover of something disposable in order to achieve clinical sanitary and safety to prevent spread of disease is conventional in the art. For example, disposable bedspread, pillow case, etc... Therefore, it would have been obvious to one of ordinary skill in the art to make the cover in Boon to be disposable as desired so that the device can be place directly beneath the patient.

Claim 14:

In Boon, the pressure pad responds to pressure by reducing electrical resistance between a first point and a second point. The apparatus including a switch armed upon the reduction of electrical resistance and an alarm for providing the alarm when the switch has been armed and the electrical resistance is under a predetermined resistance threshold, wherein a movement of the patient from the pressure pad triggers the alarm. Col. 3, third paragraph to col. 4, first paragraph.

A time delay, such as 1 second, is not disclosed in Boon, but the concept of using time delay to avoid false alarm is conventional in the art. Therefore, it would have been obvious to one skilled in the art to use a time delay in the Boon system to prevent false alarm caused by inadvertent movement of the patient.

Claim 15:

The alarm in Boon provides the alarm when the switch has been armed and electrical resistance is under the predetermined resistance threshold. Regarding the time delay between 2

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seconds and 3 seconds in duration, it is not disclosed in Boon, but the concept of using time delay to avoid false alarm is conventional in the art. Therefore, it would have been obvious to one skilled in the art to use a time delay in the Boon system to prevent false alarm caused by inadvertent movement of the patient.

7. Claims 17-20 are rejected under 35 U.S.C. 102(3) as being unpatentable over Boon (US Patent No. 5,796,059) in view of Smith, III (US Patent No. 3,737,930).

Claim 17:

Boon disclose an a pressure pad comprising an alarm system having a pressure switch 12,14, the alarm being connected to the switch, and being armed upon the pressure being placed on the pressure pad and activated upon a release of pressure of the pressure removed. Boon fails to disclose a gel cushion. Nonetheless, the use of gel cushion to provide resting comfort to patient is conventional in the art as shown in Smith, III. Therefore, it would have been obvious to one skilled to use a gel cushion with the system in Boon, by placing it on top of the pressure sensing device in Boon because it provides comfort while pressure on the gel cushion would result in pressure on the pressure switch.

Regarding the claimed preventing activating the alarm when the pressure has been on the pad for more than a predetermined time and the release of the pressure are separated in time more than a preset period of time, it would have been obvious to one skilled in the art to consider some time delays because false alarm would be preferable avoided and alarm should only be given during actual use of the pressure, whereas unintentional activation of the alarm could happen such as when health personnel might happen to press against the pad while setting up the

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bed for patient to use or inadvertent movement of patient on the bed causing false alarm to go off.

Claims 18 and 19:

Different forms of alarm indication such as visible or audible would not constitute an inventive step but a choice in design because they are functionally equivalent in providing an alert signal to a user.

Claim 20:

In Boon, the pressure switch includes two conductors spaced by a flexible material that permits contact between the conductors under a predetermined amount of pressure.

8. Claims 2, 4-5, 7-10, 13, 21-23, and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boon (US Patent No. 5,796,059) in view of Triplett et al. (US Patent No. 4,175,263).

Claims 4 and 5:

It is not clear in Boon where exactly the alarm is located. However, it would have been obvious to one skilled in the art to recognize positioning the alarm at locations because it would be convenient for monitoring staff to be alerted of the situations.

Claims 2, 21, and 22:

Boon fails to disclose a second sensor placed in juxtaposition with the patient. However, Triplett et al. teaches the use of a sensor 32 placed in juxtaposition with the patient so that when the patient assumes a dangerous position or a moving direction initiated by the patient trying to leave the bed, as indicated by the second sensor, an alarm signal is given and a monitoring

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station is activated when the alarm signal is provided, and a voice message is announced near the patient. Fig. 1. In light of this teaching, it would have been obvious to one skilled in the art to combine the features taught in Triplett in the system of Boon because it would further provide information to the care taker remote from the patient's location of the patient's dangerous position.

Claim 23:

Boon discloses a method of monitoring a patient, comprising the steps of:

- a. placing a pressure pad (including 52) on a resting place, a bed or a chair, for the patient;
- b. energizing the pressure pad, whereby a signal is provided responsive to pressure more than a predetermined pressure being placed on the pressure pad by the patient (a minimum pressure that causes the detection);
- c. applying pressure above the predetermined pressure to the pressure pad (patient lying on the pad)
- d. arming the pressure pad when the pressure more than a predetermined pressure a predetermined weight the detection is on the pressure pad whereby the pressure pad serves as a sensor;
- e. activating an alarm when the predetermined pressure has been on and then is removed from the armed pressure pad
- f. disposing of the pressure pad when the patient no longer has use of the pressure pad.

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Regarding the claimed activating the alarm when the pressure has been on the pad for more than a predetermined time and is removed from the armed pressure pad after the predetermined time, it would have been obvious to one skilled in the art to consider some time delays because false alarm would be preferable avoided and alarm should only be given during actual use of the pressure, whereas unintentional activation of the alarm could happen such as when health personnel might happen to press against the pad while setting up the bed for patient to use or inadvertent movement of patient on the bed causing false alarm to go off.

Boon fails to disclose a second sensor placed in juxtaposition with the patient. However, Triplett et al. teaches the use of a sensor placed in juxtaposition 30, 32 with the patient so that when the patient assumes a dangerous position or a moving direction initiated by the patient trying to leave the bed, as indicated by the second sensor, an alarm signal is given and a monitoring station is activated when the alarm signal is provided, and a voice message is announced near the patient. Fig. 1. In light of this teaching, it would have been obvious to one skilled in the art to combine the features taught in Triplett in the system of Boon because it would further provide information to the care taker remote from the patient's location of the patient's dangerous position or intended movement of the patient.

Claims 28 and 30:

Boon discloses a system for monitoring a patient, comprising:

- a. a pressure pad for providing a signal indicating a pressure condition;
- b. a control housing connected to the pressure pad and responsive to the signal; and
- c. a casing 52 at least partly encasing the pressure pad.

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Boon fails to disclose a second sensor. However, Triplett et al. teaches the use of a sensor 32 placed in juxtaposition with the patient so that when the patient assumes a dangerous position or a moving direction initiated by the patient trying to leave the bed, as indicated by the second sensor, an alarm signal is given and a monitoring station is activated when the alarm signal is provided, and a voice message is announced near the patient. Fig. 1. In light of this teaching, it would have been obvious to one skilled in the art to combine the features taught in Triplett in the system of Boon because it would further provide information to the care taker remote from the patient's location of the patient's dangerous position or intended movement of the patient.

*NOTE: claims 28 and 30 are exactly the same.

9. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boon (US Patent No. 5,796,059) in view of Cross (US Patent NO. 5,494,046).

Claim 13:

Boon fails to disclose a recorded voice message sounding within hearing distance of the patient. Nonetheless, such feature is conventional in the art as taught in Cross (col. 3, lines 45-50). In light of this teaching it would have been obvious to one skilled in the art to provide a verbal warning device within the hearing distance of the system in Boon for the same purpose as in Cross.

Allowable Subject Matter

10. Claims 24-27 and 29 are allowed.

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11. Claim 31 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Remarks

12. Applicant's arguments filed 2/24/03 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

2. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Wettach, US Patent No. 4,336,533, discloses a fluid activated alarm device.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Lieu whose telephone number is 703-308-6738. The examiner can normally be reached on Mon-Thursday, 9:00am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Wu can be reached on 703-308-6730. The fax phone numbers for the

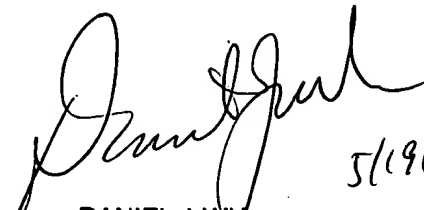
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organization where this application or proceeding is assigned are 703-872-9314 for regular communications and 703-872-9314 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3900.

Julie Lieu
Primary Examiner
Art Unit 2632

jl
May 15, 2003


5/19/03
DANIEL J. WU
PRIMARY EXAMINER